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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

SMITH, RUTH S

ART UNIT PAPER NUMBER

3737

14

DATE MAILED: 03/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/727,718

Applicant(s)

ERLACH ET AL.

Examiner

Ruth S Smith

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 11-19 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11-19 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. -

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claim Objections

Claims 2-4 are objected to because of the following informalities: It is unclear as to whether the step of inserting is part of the step of encapsulating or a completely different step. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,6,7,9,15 are rejected under 35 U.S.C. 102(b) as being anticipated by Benjamin et al ('825). Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

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were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3,5-9,14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al ('825). Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types such as red blood cells. The use of a white blood cell is merely an example disclosed by Benjamin et al. It would have been obvious to one skilled in the art that the method of Benjamin et al would be applicable to any type of cell that can be placed in vivo.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al ('825) in view of Kopelman et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Kopelman discloses inserting a microdevice or nanodevice into a cell using a known particle delivery system such as a particle gun injector. It would have been obvious to one skilled in the art to have modified Benjamin et al such that the means used to insert the device into a cell is a particle gun injector. Such a modification merely

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involves the selection of one well known means for providing for insertion of the device into a cell.

Claims 11,12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Ostensen et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Ostensen et al disclose microparticles circulating in a body and detectable by magnetic resonance for medical diagnosis. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that it is a resonance type nanodevice that is detected by magnetic resonance. Such a modification merely incorporates a well known technique for following the course of a device placed within the body.

Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Ostensen et al as applied to claim 12 above, and further in view of Chandrakumar et al. Ostensen et al disclose microparticles circulating in a body and detectable by different imaging modalities for medical diagnosis. EPR is one well known type of imaging modality. It is known, as disclosed by Chandrakumar et al to use EPR imaging whereby the molecules detected comprise transition metal complexes. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that EPR is used to detect the presence of the device in the body. Such a modification merely incorporates a well known technique for following the course of a device placed within the body.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Schechter. Benjamin et al disclose a method and system for

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injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Schechter discloses the treatment of devices placed within a body with a compound to improve biological function by reducing antigenicity and prolonging retention by the host. It would have been obvious to one skilled in the art to have further modified Benjamin et al such that the device is treated with a material to prolong retention in the body in order to prolong its use.

Claims 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benjamin et al in view of Dustin et al or Li et al. Benjamin et al disclose a method and system for injecting a microdevice into the vascular system or encapsulated into a cell (column 15, lines 33-34). Benjamin et al disclose using a microdevice carrying circuits for signal processing, the circuits containing silicon, phosphorus, providing output and transmitting information. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types. Dustin et al disclose the use of lipid anchors to enable the attachment of circulating micelles to a variety of target molecules on a cell. Furthermore, it is well known in the art that organo hydroxyls (e.g. ethylene glycol) are used as cross-linking molecules that can be modified to have little effect on the chemistry of the molecules being linked. Li et al disclose the use of ethylene glycol as a lipid anchor to enhance the attachment of circulating microparticles to reduce clearance by the reticuloendothelial system and thereby increase the medical effectiveness of the microparticles. Therefore, it would have been obvious to one skilled in the art to have modified the device such that it includes a lipid anchor to promote attachment of the device to a cell and thereby prolong its presence in a body and enhance its diagnostic or therapeutic function.

Response to Arguments

Applicant's arguments filed December 16, 2003 have been fully considered but they are not persuasive. It should be noted that while Benjamin et al disclose the use of white blood cells, the disclosure on lines 33-34 of column 15 does not preclude the use of other cell types such as red blood cells. The use of a white blood cell is merely an example disclosed by Benjamin et al. It would have been obvious to one skilled in the art that the method of Benjamin et al would be applicable to any type of cell that can be placed in vivo. It should be noted that the present form of claim 2 does not replace the term inserting with encapsulating as set forth in applicant's remarks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruth S Smith whose telephone number is (703) 308-3063. The examiner can normally be reached on M-F 5:30 AM- 2:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dennis Ruhl can be reached on (703) 308-2262. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ruth S Smith
Primary Examiner
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